Annex

QUESTIONNAIRE FOR THE TESTING OF THE GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

GENERAL INFORMATION ABOUT THE TESTING	
Q1. These results are being submitted on behalf of a:	☒ Party. Please specify: UK ☐ Other Government. Please specify: <Country's name> ☐ Organization: Please specify: <Organization's name>
Q2. When was the testing of the Guidance conducted?	Please enter date: November 2011
Q3. Type of event where the testing of the Guidance was conducted?	☐ Group event (e.g., workshop, training course, meeting). Please provide the title of the event and name of organizer: <Type here> Type of meeting: ☐ Face-to-face ☐ Online ☒ Individual exercise. Please provide your name, occupation and affiliation: Dr Louise Ball. Risk assessor in the UK competent authority for releases of LMOs into the environment and secretary to the UK advisory committee that deals with the release of GMOs into the environment.Comments are based on whether previous concerns raised by the UK or its advisory committee (ACRE) have been addressed in the latest version of the guidance. ☐ Other: Please specify: <Type here>
Q4. Which sections of the Guidance were tested?	☒ Part I: The Roadmap for Risk assessment of LMOs Part II: Specific types of LMOs or Traits: ☒ Risk assessment of LMOs with stacked genes or traits ☒ Risk assessment of LM crops with tolerance to abiotic stress ☒ Risk assessment of LM mosquitoes

OVERALL EVALUATION					
	Very poor	**Poor**	**Neutral**	**Good**	**Very good**
Please indicate the level of agreement you attribute to each of the questions in the left column.					
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	☐	☐	☐	☒	☐
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in a scientifically sound and case-by-case manner?	☐	☒	☐	☐	☐

Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs introduced into various receiving environments?	☐	☒	☐	☐	☐

PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	☐ Yes ☒ No	Comments: The Roadmap has improved significantly since the last version through simplifying and reducing the amount of text. However, it could be improved further. The guidance highlights the need for problem formulation. However, the points to consider appear disconnected from this approach. It would be very useful if the guidance provided examples as to why information such as molecular characterisation data would be useful in the risk assessment e.g. where the points to consider include information on copy number, expression levels and genotypic/ phenotypic stability. Similarly, in providing examples where persistence and geneflow may be associated with a risk. Emphasising the need to carry out steps 2 and 3 in tandem, as shown in the flow chart, will help focus on characterising risks rather than hazards (i.e. in generating information that will help decision makers).
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ☒ No	Comments: The list of points could be taken as a framework for a research project without more context. It might be difficult to see the 'wood for the trees' without more experience.
Q10. Is the Roadmap organized in a logic and structured manner?	☒ Yes ☐ No	Comments: <Type here>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments:
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ☒ No	Comments: It is applicable to plants and works less well for animals and particularly microorganisms.
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	☐ Yes ☒ No	Comments: See Q9 - it might be difficult for inexperienced assessors to differentiate between the information requirements for a trial with minimal environmental exposure and those for larger-scale release, particularly with respect to molecular characterisation data.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☒ Yes ☐ No	Comments: Previously the UK recommended that systematic approaches to RA such as tiered approaches were introduced. We also suggested the inclusion of worst-case scenarios. This is particularly useful for issues such as horizontal gene transfer .

Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☒ Yes ☐ No	Comments: <The box under step 5 is unneccessarily complex. The main question is whether there is enough information of the requisite quality to characterise the risks posed by the LMO,which in turn will allow the risk manager to reach a decision. RM strategies are developed as part of the RA and also as part of the decision-making process- do they need to be included again. New information (of potential relevance) is an issue that could arise at any point, not just in the window between the RA being completed and the decision-making process. It could be removed from this box?

PART II: SPECIFIC TYPES OF LIVING MODIFIED ORGANISMS OR TRAITS		
Risk assessment of living modified organisms with stacked genes or traits		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q16. Does this section provide useful guidance when conducting risk assessments of LMOs with stacked genes or traits in accordance with the Protocol?	☐ Yes ☒ No	Comments: We have serious reservations about the scientific credibility of this section. It conveys a lack of understanding that genomes are not fixed entities - differences/ changes are inevitable. This is compounded by a lack of problem formulation/ risk hypotheses. The guidance does not explain that some importing countries do not regulate stacked events. In addition, the scope restricts this guidance to LMOs comprising LM events that have been assessed previously. There is a strong possibility that assessors will need to consider LMOs containing multiple events in which all of the individual events have not been considered before.
Q17. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LMOs with stacked genes of traits?	☐ Yes ☒ No	Comments:
Q18. Is this section of the Guidance organized in a logic and structured manner?	☐ Yes ☒ No	Comments: <Type here>
Q19. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☒ No	Comments: <Type here>
Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☒ No	Comments: <Type here>
Risk assessment of living modified crops with tolerance to abiotic stress		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q21. Does this section provide useful guidance when conducting risk assessments of LM crops with tolerance to abiotic stress(es) in accordance with the Protocol?	☐ Yes ☒ No	Comments: This section does not add significantly to the Roadmap in terms of specific issues. It is arguable that the issues highlighted could be introduced as examples in the Roadmap (where they are already referred to e.g. altered potential to persist / invade new habitats/ selection of sites for field trials). This section of the guidance places a great deal of emphasis on the potential for unexpected pleitrophic effects conferring tolerance to additional biotic and abiotic stresses. However, it does not suggest that the molecular characterisation of the LMO might include a consideration of specificity (e.g. if a transcription factor is involved - some are very specific whereas others are not).

Q22. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM crops with tolerance to abiotic stress(es)?	☐ Yes ☐ No	Comments: <Type here>
Q23. Is this section of the Guidance organized in a logic and structured manner?	☐ Yes ☐ No	Comments: <Type here>
Q24. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments: <Type here>
Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☐ No	Comments: <Type here>

Risk assessment of living modified mosquitoes

Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

Q26. Does this section provide useful guidance when conducting risk assessments of LM mosquitoes in accordance with the Protocol?	☐ Yes ☒ No	Comments: Our previous concerns about this section remain. The document is perfunctory and fails to provide adequate details on the risk assessment or management of LM mosquitoes. Primary literature sources have been taken out of context and/or poorly understood (e.g., Benedict et al. 2008). A tiered approach to testing of LM mosquitoes must be emphasised in this sort of guidance.
Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes?	☐ Yes ☐ No	Comments: <Type here>
Q28. Is this section of the Guidance organized in a logic and structured manner?	☐ Yes ☐ No	Comments: <Type here>
Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments: <Type here>
Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☐ No	Comments: <Type here>

ADDITIONAL COMMENTS

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. <Please type your comments here>
